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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/734,237	ROZZELL ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *13,16-22,34,37-43 and 50-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14,15,23-33,35,36 and 44-49* is/are rejected.

7)☒ Claim(s) *47-49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 December 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-49, a species election of oxidoreductase, and a SEQ ID election of SEQ ID Number 77 (first protein), SEQ ID NO: 79 (second protein), and SEQ ID Number 78 (oligonucleotide) in Paper No. 12 is acknowledged.

Applicants have explicitly stated that the election of Group I and the species thereof have been made without traverse. However, Applicants' response was silent in their election with regard to the restriction of the SEQ ID Numbers. Since, Applicants have not distinctly and specifically point out the supposed errors in this restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 50-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

Additionally, claims 16-22 and 37-43 remain withdrawn as being drawn to non-elected species, there being no allowable generic or linking claim. Claims 13 and 34 are drawn to vanillyl alcohol reductase, also withdrawn for being drawn to non-elected invention (SEQ ID Numbers).

Preliminary Remark

Claims 1-12, 14, 15, 23-33, 35, 36, and 44-49 are under prosecution.

Claims 13, 16-22, 34, 37-43, and 50-72 are withdrawn from further consideration.

Priority

Applicants are advised that the claimed subject matter under prosecution (synthetic nucleic acid encoding the species of oxidoreductase, and the specific embodiment of SEQ ID Numbers 77-79) do not receive the benefit of the priority date under 35 U.S.C. 120 because the claimed subject matter is not support in the parent application, 09/494,921. The disclosure of the parent is drawn to methionine gamma-lyase and all of the disclosed SEQ ID Numbers are drawn to the gamma-lyase, rendering the instantly claimed subject matter unsupported.

Therefore, the effective filing date of the claimed subject matter under prosecution is determined to the be actual filing date of the instant application, which is December 8, 2000.

Specification

Applicants are advised that the Figures 1A-D contains nucleic acid sequences which are not described by their SEQ ID Numbers. Applicants are advised to either amend the figures to include the SEQ ID Numbers or amend the Brief Description of the Drawing to annotate the figures. If the SEQ ID Numbers have not been submitted in the originally filed Paper Copy of the Sequence Listing and the CRF, Applicants are advised to refer to section 37 CFR 1.821-1.825.

The Drawings are defective as noted in the attached PTO 948. Applicants are reminded that a fully responsive response must contain the corrected drawings.

The specification is objected to by the Examiner because it makes reference to an URL on the internet. For example, line 33 of page 9, line 22 of page 13, etc. contain web-addresses.

While information on web-address is accessible, the embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference.

If the subject matter which is improperly incorporated by reference is directed to nonessential material (illustrating the state of the art), the deletion will probably not be considered as new matter. However, if the subject matter which is improperly incorporated by reference is directed to essential material, applicant will be required to amend the specification to include the subject matter incorporated. The amendment must be accompanied by an affidavit or declaration executed by the applicant stating that the amendatory material consists of the same material incorporated by reference.

Claim Objections

Claims 47-49 are objected to for minor informalities:

A claim which depends from a dependent claim should not be separated from that dependent claim by any claim which does not also depend from the dependent claim (see MPEP 608.01(n), at 600-63; *Claim Form and Arrangement*).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 14, 15, 23-29 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-12, 14, 15, 23-25, and 27-29 are indefinite for the use of the term "non-naturally occurring polymer of nucleic acids," because it is unclear whether this term is meant to define modified polymers such as PNAs or the nucleic acid sequences which are not found in nature. For the purpose of prosecution, the term is assumed to be defined as the latter interpretation. In other words, the term is assumed to read on modified nucleic acid sequences (i.e., mutants) which are not found in nature.

Claims 23-26 are drawn to non-elected SEQ ID Numbers. Amending the claims to recite only the elected SEQ ID Numbers would overcome this rejection. Applicants are advised that amendment of claims 23 and 24 to only the elected SEQ ID number (SEQ ID No. 79) would render the claims duplicative in their scope.

Claim 47 is indefinite for the recitation of the phrase, "wherein the predicted free energy of folding per base is ***greater*** than that of the second nucleic acid sequence," because the term "greater than" does not properly define the metes and bounds of the claim wherein the claim could be exercised within the confines of the invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 27-31, and 44-49 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written description rejection.

Claims 1-10, 27-31, and 44-49 are drawn to any synthetic nucleic acid sequence comprising a non-naturally occurring polymer of nucleic acids that has no more than varying degrees of homologies to any naturally occurring nucleic acid sequence which encodes a first protein having an amino acid sequence, wherein the synthetic nucleic acid sequence encodes any second protein having an amino acid sequence, wherein the second protein's sequence being at various homologies to the amino acid sequence of the first protein, further wherein the synthetic nucleic acid sequence has a predicted free energy of folding per base that is at varying degrees which are greater than the predicted free energy of folding per base of the naturally occurring nucleic acid sequence.

The specification discloses the synthetic sequences encoding *E. coli* methionine β layse enzyme (pp. 28), oxidoreductase (pp. 29), keto reductase (pp. 30), decarboxylase (pp. 32), dehydrogenase (pp. 32), hydantoinase (pp. 33), synthases (pp. 34), also defined by their SEQ ID numbers 32, 35, 37, 39, 42, 44, 46, 48, 50, 52, 56, 60, 64, 68, 75, 79, 54, 58, 62, 66, 70, 73, and 77. However, the specification does not disclose any more naturally occurring sequences as well as the synthetic sequences that have greater predicted free energy of folding per base, to which the present claims read on. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the **filing date sought, he or she was in possession *of the invention***. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of above listed SEQ ID Numbers, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and proteins, **regardless of the complexity or simplicity of the method of isolation or production**. The specification makes it clear that Applicants at the time of filing, did not posses any and all synthetic nucleic acid of any and all genes which have greater free energy of folding per base. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is

claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

It is also noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that:

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

Therefore, only the disclosed genes of their SEQ ID numbers, but not the full breadth of the claim meet the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claims 30-33, 35, and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a synthetic nucleic acid sequence having a free energy of folding that is more positive than the its naturally occurring nucleic acid sequence, does not reasonably provide enablement for the encompassed embodiment of a synthetic nucleic acid sequence having a more negative free energy of folding. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation are summarized in In Re Wands (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). They include (A) the quantity of experimentation necessary, (B) the amount of direction or guidance presented, (C) the presence or absence of working examples, (D) the nature of the invention, (E) the state of the prior art, (F) the relative skill of those in the art, (G) the predictability or unpredictability of the art, and (H) the breadth of the claims.

A) Quantity of Experimentation: The specification discloses that the advantage of the instant invention is drawn to producing a nucleic acid sequence by replacing one or more codons in the sequence in one or more areas of predicted secondary structure with less preferred codons to reduce predicted secondary structure which results in nucleic acid templates having better properties for polymerization and amplification. The specification is completely absent in its teaching in using the claimed invention for producing a nucleic acid sequence that has lower free energy of folding, which would lead a skilled artisan to undue quantity of experimentation in practicing the full encompassed scope of the claimed invention.

B) Amount of direction or Guidance: The specification only directs and guides a skilled artisan to practice the invention in arriving at a nucleic acid sequence that has more positive free energy of folding. The specification is completely silent in its direction or guidance for a skilled artisan to use the claimed methods for finding a usage of a nucleic acid sequence produced by the claimed method which has more negative free energy of folding.

C) Absence of Working Example: The specification does not give any working example in using a nucleic acid of more negative free energy of folding produced by the claimed method.

D) Nature of Invention: The nature of the invention relates to computerized method of nucleic acid sequence modification.

E) State of prior art: The state of prior art known to a skilled artisan in the relevant field is determined to be reduction of secondary structure in primer design. But no prior art teaches the claimed method of making/designing a synthetic nucleic acid resulting in increased free energy of folding by determining the free energy of a starting nucleic acid and replacing at least one codon from the starting nucleic acid sequence with a different corresponding codon.

F) Skill level: The level of the skilled artisan in the relevant field is considered to be high.

G) Unpredictability of art: Although the claimed method of producing a synthetic nucleic acid which has a modified free energy of folding is predictably accomplished, the usage of the produced synthetic nucleic acid which has a more negative free energy of folding is unpredictable because such teachings are simply absent in the prior art or the specification of the instant application.

H) Breadth of Claims: The breadth of the claims encompasses the broad genus of method of making/designing a synthetic nucleic acid with a more negative free energy of folding. A

skilled artisan would not be able to practice the claimed method commensurate with the full scope of the invention because the teaching on using a synthetic nucleic acid with more negative free energy of folding is simply not taught in the prior art or by the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12, 14, 15, 27-33, 35, 36, and 44-49 rejected under 35 U.S.C. 102(e) as being anticipated by Delagrave et al. (US2001/0051369 A1, published December 13, 2001, priority February 25, 2000).

Claims are drawn to any synthetic nucleic acid sequence comprising a non-naturally occurring polymer of nucleic acids that has no more than varying degrees of homologies to any naturally occurring nucleic acid sequence which encodes a first protein having an amino acid sequence, wherein the synthetic nucleic acid sequence encodes any second protein having an amino acid sequence, wherein the second protein's sequence being at various homologies to the amino acid sequence of the first protein, further wherein the synthetic nucleic acid sequence has a predicted free energy of folding per base that is at varying degrees which are greater than the predicted free energy of folding per base of the naturally occurring nucleic acid sequence. An

embodiment is drawn to the second protein being an oxidoreductase enzyme, more particularly, galactose oxidase enzyme.

Delagrave et al. disclose a synthesized mutant polynucleotide encoding a polypeptide, more particularly galactose oxidase enzyme, said mutant produced by mankind (therefore, the sequence not naturally occurring), which have superior enzymatic activity and thermostability [0009], wherein said mutant is a variant of a wildtype protein, said mutation is substitutions selected from the group consisting of C383S, V494A, Q63K, and either Y436N or Y436H [0036]. Such substitutions would produce a mutant protein which show homologies within the claimed limitations.

Although Delagrave et al. do not disclose the specific claimed limitations of free energy of folding (i.e., stability), according to *In re Best* 195 USPQ 430, 1997, the court stated that, "Patent Office can require applicant to prove that prior art products do not necessarily or inherently posses characteristics of his claimed product wherein claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes; burden of proof is on applicant" (pp. 430). Because the description of Delagrave et al. explicitly teach that their nucleic acid encoding the synthetic mutant galactose oxidase enzyme is more thermostable and the structural feature (i.e., homology) anticipates the claimed structure feature, absent evidence that the disclosed protein of Delagrave et al. does not have the claimed stability, the nucleic acid of of Delagrave et al. would inherently encode the polypeptide of the claimed limitations, anticipating the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 27-31, and 44-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over SantaLucia (Proc. Natl. Acad. Sci., USA, 1998, vol. 95, pages 1460-1465).

Claims are drawn to any synthetic nucleic acid sequence comprising a non-naturally occurring polymer of nucleic acids that has no more than varying degrees of homologies to any naturally occurring nucleic acid sequence which encodes a first protein having an amino acid sequence, wherein the synthetic nucleic acid sequence encodes any second protein having an amino acid sequence, wherein the second protein's sequence being at various homologies to the amino acid sequence of the first protein, further wherein the synthetic nucleic acid sequence has a predicted free energy of folding per base that is at varying degrees which are greater than the predicted free energy of folding per base of the naturally occurring nucleic acid sequence.

SantaLucia reference discloses a method of minimizing the free energy of nucleic acid (Abstract). The specification also concedes to this fact wherein it recites, "computer program exists that can predict the secondary structure of a nucleic acid by calculating its free energy of folding...one example is the *mfold* program...using free energies derived from SantaLucia (lines 14-20, pp. 13). The specification further states that, "the predicted free energy of folding for designed sequence is calculated using a computer program as described previously...program *mfold* is used in the Examples provided herein (lines 10-11, pp. 14). Thus, SantaLucia reference discloses the method of predicting the free energy of folding of a nucleic acid. The reference,

however, does not explicitly disclose the final step of producing the physical embodiment or a "tangible" nucleic acid.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce the physical embodiment or a tangible nucleic acid derived from the method disclosed by SantaLucia because one of ordinary skill in the art would have been motivated to produce the nucleic acid for the further study of nucleic acids. Because the special attributes defined by the method producing the claimed nucleic acid is disclosed by SantaLucia, it would have been well within the purview of the ordinarily skilled artisan to use the method to produce the claimed nucleic acids with claimed limitations.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

1/23/03

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

1/27/03